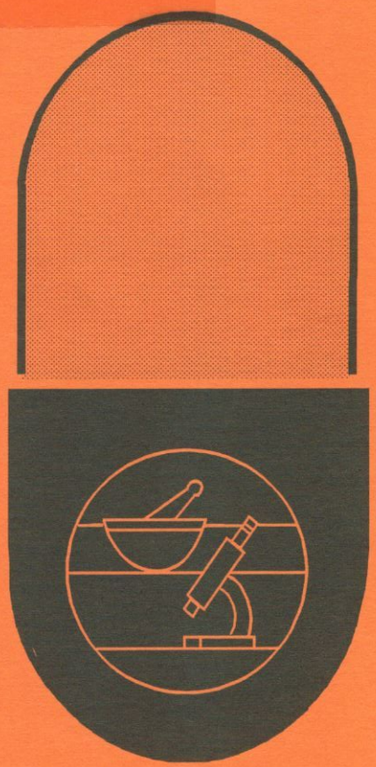
CUMULATIVE SUPPLEMENT 3
MAR'99



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGMENT AND SERVICES

1999

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

Cumulative Supplement 3

MARCH 1999

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19TH EDITION

CUMULATIVE SUPPLEMENT 3
MARCH 1999

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 19th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

New additions to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol **>DLT>** (DELETE) to the left of the line. The **>DLT>** symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition. However, the overstruck data in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements (hard copy).

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 19th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 20th Edition.

1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)

NO APPLICANT NAME CHANGES – MARCH 1999

1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Falcon Pharms' (Alcon) NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

1.4 AVAILABILITY OF THE EDITION

The 19th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is $78.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the hard copy monthly supplement is at http://www.fda.gov/cder/orange/supplement/cspreface.htm. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product prescription, OTC and discontinued data at http://www.fda.gov/cder/orange/obreadme.htm. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 19th annual edition of the 1998 Orange Book Patent and Exclusivity List is at http://www.fda.gov/cder/orange/19bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1998) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1998	MAR 1999	JUN 1999	SEP 1999
DRUG PRODUCTS LISTED	9923	9975		
SINGLE SOURCE	2504 (25.2%)	2520 (25.3%)		
MULTISOURCE	7308 (73.6%)	7344 (73.6%)		
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)	6969 (69.9%)		
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)	375 (3.8%)		
EXCEPTIONS[1]	111 (1.1%)	111 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	10	3		
NUMBER OF APPLICANTS	563	570		

[1]Amino acid-containing products of varying composition (see Introduction. page xx of the List).

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	MALLINCKRODT	500MG;5MG	N88956 001	JUL 19, 1985
	ZYDONE			
AA	MALLINCKRODT	500MG;5MG	N88956 001	JUL 19, 1985

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN

> ADD >	AA	DURAMED	500MG;5MG	N40289 001	MAR 16, 1999

TABLET; ORAL
OXYCODONE AND ACETAMINOPHEN

> ADD >	AA	AMIDE PHARM	325MG;5MG	N40203 001	MAR 15, 1999

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100

AB	TEVA	650MG;100MG	N70107 001	JUN 12, 1985
@		650MG;100MG	N70107 001	JUN 12, 1985

ACYCLOVIR

CAPSULE; ORAL
ACYCLOVIR

AB	STASON	200MG	N75090 001	JAN 26, 1999

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR SODIUM

AP	+ AM PHARM PARTNERS	EQ 50MG BASE/ML	N74930 001	MAY 13, 1998

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR SODIUM

+	AM PHARM PARTNERS	EQ 50MG BASE/ML	N74930 001	MAY 13, 1998
AP	MERIDIAN MEDCL TECHN	EQ 50MG BASE/ML	N75065 001	FEB 25, 1999

ALBUTEROL

AEROSOL, METERED; INHALATION
ALBUTEROL

AB	MEDEVA	0.09MG/INH	N72273 001	AUG 14, 1996
AB	MEDEVA PHARMS MA	0.09MG/INH	N72273 001	AUG 14, 1996

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

AN	HI TECH PHARMA	EQ 0.083% BASE	N75063 001	FEB 09, 1999

SYRUP; ORAL
ALBUTEROL SULFATE

> ADD >	AA	UDL	EQ 2MG BASE/5ML	N75262 001	MAR 30, 1999

ALITRETINOIN

GEL; TOPICAL
PANRETIN

+	LIGAND	EQ 0.1% BASE	N20886 001	FEB 02, 1999

ALLOPURINOL

TABLET; ORAL
ZYLOPRIM

AB	FARO PHARMS	100MG	N16084 001	
AB	+	300MG	N16084 002	
AB	GLAXO WELLCOME	100MG	N16084 001	
AB	+	300MG	N16084 002	

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL

AB	ALPHAPHARM	200MG	N75188 001	FEB 24, 1999

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL
BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE

> ADD >	AB	ENDO PHARMS	325MG;50MG;40MG;30MG	N75351 001	MAR 05, 1999
> ADD >					

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL W/ ATROPINE SULFATE

> ADD >	AA	ZENITH GOLDLINE	0.025MG;2.5MG	N86727 001	
> DLT >		Ø	0.025MG;2.5MG	N86727 001	

BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL
CORZIDE

	APOTHECON	5MG;40MG	N18647 001	MAY 25, 1983
+		5MG;80MG	N18647 002	MAY 25, 1983
	BRISTOL MYERS SQUIBB	5MG;40MG	N18647 001	MAY 25, 1983
+		5MG;80MG	N18647 002	MAY 25, 1983

BETAMETHASONE VALERATE

AEROSOL; TOPICAL
LUXIQ

+	CONNETICS	EQ 0.12% BASE	N20934 001	FEB 28, 1999

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
WELLBUTRIN

+	GLAXO WELLCOME	50MG	N20358 001	OCT 04, 1996
+		100MG	N20358 002	OCT 04, 1996
+		150MG	N20358 003	OCT 04, 1996

WELLBUTRIN SR

+	GLAXO WELLCOME	50MG	N20358 001	OCT 04, 1996
+		100MG	N20358 002	OCT 04, 1996
+		150MG	N20358 003	OCT 04, 1996

BUSULFAN

INJECTABLE; INJECTION
BUSULFEX

+	ORPHAN MEDCL	6MG/ML	N20954 001	FEB 04, 1999

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION
ENDOSOL EXTRA

> ADD >	AT	AKORN	0.154MG/ML;0.92MG/ML;0.184MG/ML;		
> ADD >			0.2MG/ML;0.38MG/ML;2.1MG/ML;		
> ADD >			7.14MG/ML;0.42MG/ML	N20079 001	NOV 27, 1991
> ADD >					
> DLT >	AT	ALLERGAN	0.154MG/ML;0.92MG/ML;0.184MG/ML;		
> DLT >			0.2MG/ML;0.38MG/ML;2.1MG/ML;		
> DLT >			7.14MG/ML;0.42MG/ML	N20079 001	NOV 27, 1991
> DLT >					

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION
ISOLYTE R W/ DEXTROSE 5% IN PLASTIC CONTAINER

	B BRAUN	37MG/100ML;5GM/100ML;31MG/100ML; 120MG/100ML;330MG/100ML; 88MG/100ML	N18271 001
	@	37MG/100ML;5GM/100ML;31MG/100ML; 120MG/100ML;330MG/100ML; 88MG/100ML	N18271 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION
ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER

	B BRAUN	35MG/100ML;5GM/100ML;30MG/100ML; 74MG/100ML;640MG/100ML;500MG/100ML; 74MG/100ML	N18269 002 JAN 17, 1983
	@	35MG/100ML;5GM/100ML;30MG/100ML; 74MG/100ML;640MG/100ML;500MG/100ML; 74MG/100ML	N18269 002 JAN 17, 1983

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
CHLORPROMAZINE HCL

AA	PHARM ASSOC	**100MG/ML**	**N40224 001**	JAN 26, 1999

CHOLESTYRAMINE

POWDER; ORAL
CHOLESTYRAMINE LIGHT

>ADD>	**AB**	COPLEY PHARM	**EQ 4GM RESIN/SCOOPFUL**	**N74555 002** SEP 30, 1998
>ADD>				

CILOSTAZOL

TABLET; ORAL
PLETAL

	+	OTSUKA	50MG	N20863 001 JAN 15, 1999

CILOSTAZOL

TABLET; ORAL
PLETAL

	+	OTSUKA	100MG	N20863 002 JAN 15, 1999

CLOBETASOL PROPIONATE

SOLUTION; TOPICAL
CLOBETASOL PROPIONATE

AT		ALTANA	**0.05%**	**N75391 001** FEB 08, 1999

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION
COLISTIMETHATE

AP		PHARMA TEK	**EQ 150MG BASE/VIAL**	**N64216 001** FEB 26, 1999

COLY-MYCIN M

AP	+	PARKEDALE	**EQ 150MG BASE/VIAL**	**N50108 002**
	+		EQ 150MG BASE/VIAL	N50108 002

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DDAVP

AB	+	RHONE POULENC RORER	**0.01MG/SPRAY**	**N17922 003** AUG 07, 1996
	+		0.01MG/SPRAY	N17922 003 AUG 07, 1996

DESMOPRESSIN ACETATE

AB		BAUSCH AND LOMB	**0.01MG/SPRAY**	**N74830 001** JAN 25, 1999

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
MAXITROL

AT	+	ALCON	**0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM**	**N50065 002**
AT	+	FALCON PHARMS	**0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM**	**N50065 002**

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

		MAXITROL			
AT	+	ALCON	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N50023 002	
AT	+	FALCON PHARMS	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N50023 002	> ADD > > ADD >

DIAZEPAM

GEL; RECTAL

	DIASTAT			
	+ ATHENA	2.5MG/0.5ML	N20648 001 JUL 29, 1997	
		5MG/ML	N20648 002 JUL 29, 1997	
		10MG/2ML	N20648 003 JUL 29, 1997	
		15MG/3ML	N20648 004 JUL 29, 1997	
	+	20MG/4ML	N20648 005 JUL 29, 1997	> DLT > > DLT >
	+ ELAN PHARMS	2.5MG/0.5ML	N20648 001 JUL 29, 1997	> ADD > > ADD >
		5MG/ML	N20648 002 JUL 29, 1997	
		10MG/2ML	N20648 003 JUL 29, 1997	
		15MG/3ML	N20648 004 JUL 29, 1997	
	+	20MG/4ML	N20648 005 JUL 29, 1997	> ADD > > ADD > > DLT > > DLT >

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

	DICLOFENAC SODIUM		
AB	ALCON	0.1%	N20809 001 MAY 04, 1998
AB	FALCON PHARMS	0.1% †	N20809 001 MAY 04, 1998

TABLET, DELAYED RELEASE; ORAL

	DICLOFENAC SODIUM		
AB	MARTEC	50MG	N74986 001 FEB 26, 1999

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

	DICLOFENAC SODIUM		
AB	MARTEC	75MG	N74986 002 FEB 26, 1999
AB	NOVOPHARM	50MG	N74723 001 MAR 30, 1999

DICYCLOMINE HYDROCHLORIDE

TABLET; ORAL

	DICYCLOMINE HCL		
AB	LANNETT	20MG	N40230 001 FEB 26, 1999

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

	DIPIVEFRIN HCL		
AT	ALCON	0.1%	N73636 001 JUN 30, 1994
AT	FALCON PHARMS	0.1%	N73636 001 JUN 30, 1994

DIPYRIDAMOLE

TABLET; ORAL

	DIPYRIDAMOLE		
AB	PUREPAC PHARM	25MG	N89425 001 JUL 12, 1990
	@	25MG	N89425 001 JUL 12, 1990

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL

	DYNABAC		
	+ LILLY	250MG	N50678 001 JUN 19, 1995
	+ SANOFI	250MG	N50678 001 JUN 19, 1995

† SEE SECTION 1.3 OF INTRODUCTION

† SEE SECTION 1.3 OF INTRODUCTION

EPINEPHRINE

INJECTABLE; INJECTION
SUS-PHRINE
\+ FOREST LABS 5MG/ML N07942 001
SUS-PHRINE SULFITE-FREE
FOREST LABS 1.5MG/AMP N07942 003
FEB 05, 1999
\+ 5MG/ML N07942 001

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA
> ADD > BX + BERLEX LABS 0.025MG/24HR N20375 004
> ADD > MAR 05, 1999

> ADD > TABLET; VAGINAL
> ADD > VAGIFEM
> ADD > + NOVO NORDISK 25 UGM N20908 001
> ADD > MAR 26, 1999

> ADD > ESTROGENS, CONJUGATED SYNTHETIC A

> ADD > TABLET; ORAL
> ADD > CENESTIN
> ADD > DURAMED 0.625MG N20992 002
> ADD > MAR 24, 1999
> ADD > 0.9MG N20992 003
> ADD > MAR 24, 1999

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
BREVICON 21-DAY
AB SEARLE 0.035MG;0.5MG N17566 001 > ADD >
AB WATSON LABS 0.035MG;0.5MG N17566 001 > ADD >
NORINYL 1+35 21-DAY
AB SEARLE 0.035MG;1MG N17565 001
AB WATSON LABS 0.035MG;1MG N17565 001
TRI-NORINYL 21-DAY
\+ SEARLE 0.035MG,0.035MG;0.5MG,1MG N18977 001 > ADD >
APR 13, 1984 > ADD >
\+ WATSON LABS 0.035MG,0.035MG;0.5MG,1MG N18977 001 > ADD >
APR 13, 1984 > ADD >

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28
BREVICON 28-DAY
AB SEARLE 0.035MG;0.5MG N17743 001
AB WATSON LABS 0.035MG;0.5MG N17743 001
NORINYL 1+35 28-DAY
AB SEARLE 0.035MG;1MG N17565 002
AB WATSON LABS 0.035MG;1MG N17565 002
TRI-NORINYL 28-DAY
SEARLE 0.035MG,0.035MG;0.5MG,1MG N18977 002
APR 13, 1984
WATSON LABS 0.035MG,0.035MG;0.5MG,1MG N18977 002
APR 13, 1984

ETOPOSIDE

INJECTABLE; INJECTION
VEPESID
AP * BRISTOL 20MG/ML N18768 001
NOV 10, 1983
AP + BRISTOL MYERS SQUIBB 20MG/ML N18768 001
NOV 10, 1983

FERRIC SODIUM GLUCONATE

INJECTABLE; INJECTION
FERRLECIT
\+ R AND D LABS 62.5MG/5ML N20955 001
FEB 18, 1999

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
AP BIGMAR 50MG/ML N40291 001
MAR 24, 1999

FLUOXETINE HYDROCHLORIDE

TABLET; ORAL
PROZAC
LILLY EQ 10MG BASE N20974 001
MAR 09, 1999

FLUOXETINE HYDROCHLORIDE

> ADD >		TABLET; ORAL			
> ADD >		PROZAC			
> ADD >		+ LILLY	EQ 20MG BASE	N20974 002	
> ADD >				MAR 09, 1999	

GENTAMICIN SULFATE

		SOLUTION/DROPS; OPHTHALMIC		
		GENTAMICIN SULFATE		
> DLT >	**AT**	**ALCON**	**EQ 0.3% BASE**	**N62196 001**
> ADD >	**AT**	FALCON PHARMS	**EQ 0.3% BASE**	**N62196 001**

GLYCOPYRROLATE

		TABLET; ORAL		
		ROBINUL		
> ADD >		+ HORIZON PHARM	1MG	N12827 001
> DLT >		+ ROBINS AH	1MG	N12827 001
		ROBINUL FORTE		
> ADD >		+ HORIZON PHARM	2MG	N12827 002
> DLT >		+ ROBINS AH	2MG	N12827 002

HYDROCHLOROTHIAZIDE; IRBESARTAN

		TABLET; ORAL		
> ADD >		AVALIDE		
> ADD >		@ SANOFI	12.5MG;75MG	N20758 001
> ADD >				SEP 30, 1997
> ADD >			12.5MG;150MG	N20758 002
> ADD >				SEP 30, 1997
> ADD >		+	12.5MG;300MG	N20758 003
> ADD >				AUG 31, 1998
> DLT >		AVAPRO HCT		
> DLT >		@ SANOFI	12.5MG;75MG	N20758 001
> DLT >				SEP 30, 1997
> DLT >		+	12.5MG;150MG	N20758 002
> DLT >				SEP 30, 1997

HYDROXYUREA

		CAPSULE; ORAL		
		HYDROXYUREA		
	AB	PAR PHARM	500MG	N75340 001
				FEB 24, 1999

IBUPROFEN

		SUSPENSION; ORAL		
		MOTRIN		
	AB	+ MCNEIL	100MG/5ML	**N19842 001**
				SEP 19, 1989
	AB	+ MCNEIL CONS	100MG/5ML	**N19842 001**
				SEP 19, 1989
		TABLET; ORAL		
		MOTRIN		
	AB	MCNEIL	300MG	**N17463 003**
	AB		400MG	**N17463 002**
	AB		600MG	**N17463 004**
	AB	+	800MG	**N17463 005**
				MAY 22, 1985
			100MG	N20418 001
				NOV 16, 1994
	AB	MCNEIL CONS	300MG	**N17463 003**
	AB		400MG	**N17463 002**
	AB		600MG	**N17463 004**
	AB	+	800MG	**N17463 005**
				MAY 22, 1985
			100MG	N20418 001
				NOV 16, 1994
		TABLET, CHEWABLE; ORAL		
		MOTRIN		
		MCNEIL	50MG	N20135 001
				NOV 16, 1994
		+	100MG	N20135 002
				NOV 16, 1994
		MCNEIL CONS	50MG	N20135 001
				NOV 16, 1994
		+	100MG	N20135 002
				NOV 16, 1994

ISOETHARINE HYDROCHLORIDE

		SOLUTION; INHALATION		
		ISOETHARINE HCL		
	AN	INTL MEDICATION	0.08%	**N86651 002**
	AN		0.1%	**N86651 003**
	AN	+	0.1%	**N86651 003**
	AN		0.167%	**N86651 005**
	AN	+	0.167%	**N86651 005**
	AN		0.25%	**N86651 007**
	AN	+	0.25%	**N86651 007**

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

		ISOETHARINE HCL			
	+	INTL MEDICATION	0.08%		N86651 002
		ISOETHARINE HCL S/F			
AN	+	DEY	**0.08%**		**N89817 001**
					NOV 22, 1988
AN	+		**0.1%**		**N89818 001**
					NOV 22, 1988
AN	+		**0.17%**		**N89819 001**
					NOV 22, 1988
AN	+		**0.25%**		**N89820 001**
					NOV 22, 1988
	@		0.08%		N89817 001
					NOV 22, 1988
	@		0.1%		N89818 001
					NOV 22, 1988
	@		0.17%		N89819 001
					NOV 22, 1988
	@		0.25%		N89820 001
					NOV 22, 1988

ISOSORBIDE DINITRATE

TABLET; ORAL

		SORBITRATE			
>_DLT_>	**AB**	ZENECA	**30MG**		**N88124 001**
>_DLT_>					AUG 21, 1990
>_ADD_>		@	30MG		N88124 001
>_ADD_>					AUG 21, 1990

ITRACONAZOLE

INJECTABLE; INJECTION

		SPORANOX			
>_ADD_>		+ JANSSEN	10MG/ML		N20966 001
>_ADD_>					MAR 30, 1999

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

		KETOPROFEN			
>_ADD_>	**AB**	ANDRX PHARMS	**100MG**		**N75270 002**
>_ADD_>					MAR 24, 1999

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

		KETOPROFEN			
>_ADD_>	**AB**	ANDRX PHARMS	**150MG**		**N75270 003**
>_ADD_>					MAR 24, 1999
>_ADD_>	**AB**		**200MG**		**N75270 001**
>_ADD_>					MAR 24, 1999
		ORUVAIL			
>_ADD_>	**AB**	WYETH AYERST	**100MG**		**N19816 003**
>_ADD_>					FEB 08, 1995
>_ADD_>	**AB**		**150MG**		**N19816 002**
>_ADD_>					FEB 08, 1995
>_DLT_>			100MG		N19816 003
>_DLT_>					FEB 08, 1995
>_DLT_>			150MG		N19816 002
>_DLT_>					FEB 08, 1995

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

		KETOROLAC TROMETHAMINE			
	AP	ABBOTT	**15MG/ML**		**N74993 001**
					JAN 27, 1999
	AP		**30MG/ML**		**N74993 002**
					JAN 27, 1999

LABETALOL HYDROCHLORIDE

TABLET; ORAL

		TRANDATE			
	AB	FARO PHARMS	**100MG**		**N18716 001**
					MAY 24, 1985
	AB		**200MG**		**N18716 002**
					AUG 01, 1984
	AB		**300MG**		**N18716 003**
					AUG 01, 1984
	@		400MG		N18716 004
					AUG 01, 1984
	AB	GLAXO WELLCOME	**100MG**		**N18716 001**
					MAY 24, 1985
	AB		**200MG**		**N18716 002**
					AUG 01, 1984
	AB		**300MG**		**N18716 003**
					AUG 01, 1984
	@		400MG		N18716 004
					AUG 01, 1984

LAMIVUDINE

SOLUTION; ORAL
EPIVIR-HBV
+ GLAXO WELLCOME 5MG/ML N21004 001 DEC 08, 1998
+ 5MG/ML N20596 002 DEC 08, 1998

TABLET; ORAL
EPIVIR-HBV
+ GLAXO WELLCOME 100MG N21003 001 DEC 08, 1998
+ 100MG N20564 002 DEC 08, 1998

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
AP + ABBOTT EQ 10MG BASE/ML N40147 001 JUN 25, 1997
AP + BEDFORD EQ 200MG BASE/VIAL N40056 001 MAY 23, 1995

LEUCOVORIN CALCIUM PRESERVATIVE FREE
AP + ABBOTT EQ 10MG BASE/ML N40147 001 JUN 25, 1997
AP + BEDFORD EQ 200MG BASE/VIAL N40056 001 MAY 23, 1995
AP BIGMAR EQ 10MG BASE/ML N40286 001 FEB 26, 1999
AP EQ 200MG BASE/VIAL N40258 001 FEB 26, 1999

TABLET; ORAL
LEUCOVORIN CALCIUM
>ADD< AB INVAMED EQ 15MG BASE N75327 001 MAR 24, 1999
>ADD<

>ADD< LEVALBUTEROL HYDROCHLORIDE

>ADD< SOLUTION; INHALATION
>ADD< XOPENEX
>ADD< + SEPRACOR EQ 0.021% BASE N20837 001 MAR 25, 1999
>ADD<
>ADD< + EQ 0.042% BASE N20837 002 MAR 25, 1999
>ADD<

>ADD<
>ADD<
>ADD<
>ADD<

LIDOCAINE

FILM, EXTENDED RELEASE; TRANSDERMAL
LIDODERM
+ HIND HLTHCARE 700MG/12HR N20612 001 MAR 19, 1999

LIDOCAINE; PRILOCAINE

AEROSOL; TOPICAL
EMLA
+ ASTRA PHARMS 2.5%;2.5% N20962 001 FEB 04, 1998

DISC; TOPICAL
EMLA
+ ASTRA PHARMS 2.5%;2.5% N20962 001 FEB 04, 1998

LISINOPRIL

TABLET; ORAL
ZESTRIL
ZENECA 30MG N19777 006 JAN 20, 1999

LITHIUM CARBONATE

CAPSULE; ORAL
LITHONATE
AB SOLVAY 300MG N16782 001
@ 300MG N16782 001

TABLET; ORAL
LITHIUM CARBONATE
AB PFIZER 300MG N16834 001
AB + 300MG N16834 001
LITHOTABS
AB + SOLVAY 300MG N16980 001
@ 300MG N16980 001

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
DEMEROL
AP + ABBOTT 25MG/ML N05010 007

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

			DEMEROL			
	AP	+	ABBOTT	50MG/ML	N05010 002	
	AP	+		75MG/ML	N05010 009	
	AP	+		100MG/ML	N05010 003	
	AP	+	SANOFI	25MG/ML	N05010 007	
	AP	+		50MG/ML	N05010 002	
	AP	+		75MG/ML	N05010 009	
	AP	+		100MG/ML	N05010 003	
> DLT >			MEPERIDINE HCL			
> DLT >	AP	+	ABBOTT	10MG/ML	N88432 001	
> DLT >					AUG 16, 1984	
> DLT >	AP		ASTRA PHARMS	10MG/ML	N81002 001	
> DLT >					JUL 30, 1993	
> DLT >	AP		INTL MEDICATION	10MG/ML	N81309 001	
> DLT >					AUG 30, 1993	
> DLT >	AP		MALLINCKRODT	10MG/ML	N40163 001	
> DLT >					MAY 12, 1997	
> DLT >	AP		STERIS	10MG/ML	N73443 001	
> DLT >					MAR 17, 1992	
> ADD >			MEPERIDINE HCL PRESERVATIVE FREE			
> ADD >	AP	+	ABBOTT	10MG/ML	N88432 001	
> ADD >					AUG 16, 1984	
> ADD >	AP		ASTRA PHARMS	10MG/ML	N81002 001	
> ADD >					JUL 30, 1993	
> ADD >	AP		FAULDING	10MG/ML	N40305 001	
> ADD >					MAR 10, 1999	
> ADD >	AP		INTL MEDICATION	10MG/ML	N81309 001	
> ADD >					AUG 30, 1993	
> ADD >	AP		MALLINCKRODT	10MG/ML	N40163 001	
> ADD >					MAY 12, 1997	
> ADD >	AP		STERIS	10MG/ML	N73443 001	
> ADD >					MAR 17, 1992	

SYRUP; ORAL

			DEMEROL			
	AA	+	ABBOTT	50MG/5ML	N05010 005	
	AA	+	SANOFI	50MG/5ML	N05010 005	

TABLET; ORAL

			DEMEROL			
	AA	+	ABBOTT	50MG	N05010 001	
	AA	+		100MG	N05010 004	
	AA	+	SANOFI	50MG	N05010 001	
	AA	+		100MG	N05010 004	

METHOTREXATE SODIUM

INJECTABLE; INJECTION

			METHOTREXATE			
	AP		BIGMAR	EQ 25MG BASE/ML	N40263 001	
					FEB 26, 1999	
			METHOTREXATE PRESERVATIVE FREE			
	AP		BIGMAR	EQ 25MG BASE/ML	N40265 001	
					FEB 26, 1999	
	AP			EQ 1GM BASE/VIAL	N40266 001	
					FEB 26, 1999	
			METHOTREXATE SODIUM			
		+	LEDERLE	EQ 1GM BASE/VIAL	N11719 009	
					APR 07, 1988	
			METHOTREXATE SODIUM PRESERVATIVE FREE			
	AP	+	LEDERLE	EQ 1GM BASE/VIAL	N11719 009	
					APR 07, 1988	

METHOTRIMEPRAZINE

INJECTABLE; INJECTION

			LEVOPROME			
		+	IMMUNEX	20MG/ML	N15865 001	
		@		20MG/ML	N15865 001	

METHOXSALEN

INJECTABLE; INJECTION

			UVADEX			
		+	THERAKOS	0.02MG/ML	N20969 001	
					FEB 25, 1999	

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

			MINOCYCLINE HCL			
> ADD >	AB		GLOBAL PHARM	EQ 50MG BASE	N65005 001	
> ADD >					MAR 23, 1999	
> ADD >	AB			EQ 100MG BASE	N65005 002	
> ADD >					MAR 23, 1999	

NADOLOL

TABLET; ORAL
CORGARD

AB		APOTHECON	20MG	N18063 005	
				OCT 28, 1986	
AB			40MG	N18063 001	
AB			80MG	N18063 002	
AB			120MG	N18063 003	
AB	+		160MG	N18063 004	
AB		BRISTOL MYERS SQUIBB	20MG	N18063 005	
				OCT 28, 1986	
AB			40MG	N18063 001	
AB			80MG	N18063 002	
AB			120MG	N18063 003	
AB	+		160MG	N18063 004	

NITROGLYCERIN

OINTMENT; TRANSDERMAL
NITROGLYCERIN

		ALTANA	2%	N87355 001
				JUL 08, 1988
	+		2%	N87355 001
				JUL 08, 1988

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
PRILOSEC

> DLT >		+ ASTRA PHARMS	10MG	N19810 003	> DLT >
> DLT >				OCT 05, 1995	
> ADD >			10MG	N19810 003	
> ADD >				OCT 05, 1995	> ADD >

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL
ZOFRAN ODT

		GLAXO WELLCOME	EQ 4MG BASE	N20781 001
				JAN 27, 1999
	+		EQ 8MG BASE	N20781 002
				JAN 27, 1999

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

AB	KIEL	100MG	N40249 001
			JAN 29, 1999

OXYBUTYNIN CHLORIDE

SYRUP; ORAL
OXYBUTYNIN CHLORIDE

AA	MIKART	5MG/5ML	N75039 001
			JAN 29, 1999

PAROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PAXIL CR

+	SMITHKLINE BEECHAM	EQ 12.5MG BASE	N20936 001
			FEB 16, 1999
+		EQ 25MG BASE	N20936 002
			FEB 16, 1999

PEMOLINE

TABLET; ORAL
CYLERT

AB	ABBOTT	37.5MG	N16832 002
AB	+	75MG	N16832 003
		18.75MG	N16832 001
		37.5MG	N16832 002
	+	75MG	N16832 003
	+	18.75MG	N16832 001

PEMOLINE

AB	COPLEY PHARM	37.5MG	N75030 001
			JAN 29, 1999
AB		75MG	N75030 002
			JAN 29, 1999

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL
PENTOXIL

				> ADD >
				> ADD >
AB		UPSHER SMITH	400MG	N74962 001
				MAR 31, 1999
				> ADD >

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

		FASTIN				
AA	+	SMITHKLINE BEECHAM	**30MG**	**N17352 001**		
	@		30MG	N17352 001		
		PHENTERMINE HCL				
AA		EON	**30MG**	**N86945 001**	> DLT >	
				JUL 20, 1983	> ADD >	
AA	+		**30MG**	**N86945 001**		
				JUL 20, 1983		

POLYETHYLENE GLYCOL 3350

POWDER FOR RECONSTITUTION; ORAL

	MIRALAX			
+	BRAINTREE	17GM/SCOOPFUL	N20698 001	
			FEB 18, 1999	

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC

		TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE			
> DLT >	**AT**	ALCON	**10,000 UNITS/ML;**		
> DLT >			**EQ 1MG BASE/ML**	**N64211 001**	
> DLT >				APR 13, 1998	
> ADD >	**AT**	FALCON PHARMS	**10,000 UNITS/ML;**		
> ADD >			**EQ 1MG BASE/ML**	**N64211 001**	
> ADD >				APR 13, 1998	

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

	ECONOPRED PLUS			
AB	ALCON	**1%**	**N17469 001**	
AB	FALCON PHARMS	**1%**	**N17469 001**	

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

	HYDELTRASOL			
+	MERCK	EQ 20MG PHOSPHATE/ML	N11583 002	
@		EQ 20MG PHOSPHATE/ML	N11583 002	

PROBENECID

TABLET; ORAL

		BENEMID				
AB	+	MERCK	**500MG**	**N07898 004**	> DLT >	
	@		500MG	N07898 004	> ADD >	
		PROBENECID				
AB		MYLAN	**500MG**	**N84211 002**	> DLT >	
AB	+		**500MG**	**N84211 002**	> ADD >	

PROPOFOL

INJECTABLE; INJECTION

	DIPRIVAN			
AB	+ ZENECA	**10MG/ML**	**N19627 002**	
			JUN 11, 1996	
+		10MG/ML	N19627 002	
			JUN 11, 1996	
	PROPOFOL			
AB	GENSIA SICOR PHARMS	**10MG/ML**	**N75102 001**	
			JAN 04, 1999	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

	RANITIDINE HCL			
AB	PAR PHARM	**EQ 150MG BASE**	**N75180 001**	
			JAN 28, 1999	
AB		**EQ 300MG BASE**	**N75180 002**	
			JAN 28, 1999	

RISPERIDONE

TABLET; ORAL

RISPERDAL			
+ JANSSEN	0.05MG	N20272 007	
		JAN 27, 1999	

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

ELDEPRYL			
@ SOMERSET	5MG	N19334 001	
		JUN 05, 1989	

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
SELEGILINE HCL

AB	+ SOMERSET	5MG	N19334 001 JUN 05, 1989	> ADD >	

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

AB	PUREPAC PHARM	25MG	N87998 001 OCT 14, 1983		
	@	25MG	N87998 001 OCT 14, 1983	> ADD >	
				> DLT >	

TACROLIMUS

CAPSULE; ORAL
PROGRAF

> DLT >	+ FUJISAWA HLTHCARE	EQ 1MG BASE	N50708 001 APR 08, 1994	> ADD >	
> DLT >				> DLT >	
> ADD >		EQ 0.5MG BASE	N50708 003 AUG 24, 1998		
> ADD >					
> ADD >		EQ 1MG BASE	N50708 001 APR 08, 1994		
> ADD >					

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
A-N STANNOUS AGGREGATED ALBUMIN

> DLT >	@ NORTH AM CHEMS	N/A	N17916 001		
> ADD >	@ SYNCOR PHARMS	N/A	N17916 001		
	PULMOLITE				
> ADD > BS	CIS	N/A	N17776 001		
> DLT > BS	DUPONT PHARMS	N/A	N17776 001		

TECHNETIUM TC-99M ALBUMIN COLLOID KIT

INJECTABLE; INJECTION
MICROLITE

> ADD >	CIS	N/A	N18263 001 MAR 25, 1983		
> ADD >					
> DLT >	DUPONT PHARMS	N/A	N18263 001 MAR 25, 1983		
> DLT >					

TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION
HEPATOLITE

	CIS	N/A	N18467 001 MAR 16, 1982	> ADD >	
				> ADD >	
	DUPONT PHARMS	N/A	N18467 001 MAR 16, 1982	> DLT >	
				> DLT >	

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
OSTEOLITE

AP	CIS	N/A	N17972 001	> ADD >	
AP	DUPONT PHARMS	N/A	N17972 001	> DLT >	

TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

INJECTABLE; INJECTION
PYROLITE

	CIS	N/A	N17684 001	> ADD >	
	DUPONT PHARMS	N/A	N17684 001	> DLT >	

THEOPHYLLINE

INJECTABLE; INJECTION

THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER			
@ B BRAUN	40MG/100ML	N19083 001 NOV 07, 1984	
@ MCGAW	40MG/100ML	N19083 001 NOV 07, 1984	
THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER			
@ B BRAUN	80MG/100ML	N19083 002 NOV 07, 1984	
@ MCGAW	80MG/100ML	N19083 002 NOV 07, 1984	
THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER			
@ B BRAUN	160MG/100ML	N19083 003 NOV 07, 1984	
@ MCGAW	160MG/100ML	N19083 003 NOV 07, 1984	

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

		THIOTHIXENE HCL		
AA		ALPHARMA	EQ 5MG BASE/ML	N70969 001 OCT 16, 1987
	@		EQ 5MG BASE/ML	N70969 001 OCT 16, 1987

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC

		TIMOLOL MALEATE		
AB		ALCON	EQ 0.25% BASE	N20963 001 OCT 21, 1998
AB		FALCON PHARMS	EQ 0.25% BASE	N20963 001 OCT 21, 1998

SOLUTION/DROPS; OPHTHALMIC

		TIMOLOL MALEATE		
AT		ADV REMEDIES	EQ 0.5% BASE	N74466 001 MAR 25, 1997
AT		AKORN	EQ 0.5% BASE	N74466 001 MAR 25, 1997
> DLT > AT		ALCON	EQ 0.25% BASE	N74261 001 APR 28, 1995
> DLT > AT			EQ 0.5% BASE	N74262 001 APR 28, 1995
> ADD >	@	FALCON PHARMS	EQ 0.25% BASE	N74261 001 APR 28, 1995
> ADD >	@		EQ 0.5% BASE	N74262 001 APR 28, 1995

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

		TOBREX		
AT	+	ALCON	0.3%	N50541 001
AT	+	FALCON PHARMS	0.3%	N50541 001

TRETINOIN

SOLUTION; TOPICAL

		TRETINOIN		
AT		MORTON GROVE	0.05%	N75260 001 JAN 25, 1999

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

TABLET; ORAL

		SULFA-TRIPLE #2		
AB	+	GLOBAL PHARM	167MG;167MG;167MG	N80079 001
> ADD >	@		167MG;167MG;167MG	N80079 001
		TRIPLE SULFOID		
AB		PAL PAK	167MG;167MG;167MG	N80094 001
> ADD >	+		167MG;167MG;167MG	N80094 001

UREA, C-13

POWDER FOR RECONSTITUTION; ORAL

	PYLORI-CHEK BREATH TEST		
+	ALIMENTERICS	100MG/VIAL	N20900 001 FEB 04, 1999

VALRUBICIN

	SOLUTION;		
	VALSTAR PRESERVATIVE FREE		
+	ANTHRA	40MG/ML	N20892 001 SEP 25, 1998

SOLUTION; INTRAVESICAL

	VALSTAR PRESERVATIVE FREE		
+	ANTHRA	40MG/ML	N20892 001 SEP 25, 1998

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN

>_ADD_>	ASCENT PEDS	120MG	N18337 003	
>_ADD_>			SEP 12, 1983	
>_ADD_>		325MG	N18337 002	
>_ADD_>		650MG	N18337 001	
>_DLT_>	UPSHER SMITH	120MG	N18337 003	
>_DLT_>			SEP 12, 1983	
>_DLT_>		325MG	N18337 002	
>_DLT_>		650MG	N18337 001	

CLOTRIMAZOLE

CREAM; TOPICAL
LOTRIMIN AF

	SCHERING PLOUGH	1%	N17619 002
			OCT 27, 1989

LOTION; TOPICAL
LOTRIMIN AF

	SCHERING	1%	N18813 002
			OCT 27, 1989

SOLUTION; TOPICAL
LOTRIMIN AF

	SCHERING PLOUGH	1%	N17613 002
			OCT 27, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>_ADD_>	LNK	200MG	N75010 001
>_ADD_>			MAR 01, 1999
>_ADD_>		200MG	N75139 001
>_ADD_>			MAR 01, 1999

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICOTINE POLACRILEX

>_ADD_>	CIRCA	EQ 2MG BASE	N74507 001
>_ADD_>			MAR 15, 1999

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICOTINE POLACRILEX

>_ADD_>	CIRCA	EQ 4MG BASE	N74707 001
>_ADD_>			MAR 19, 1999

NONOXYNOL-9

SPONGE; VAGINAL
TODAY

>_ADD_>	@ ALLENDALE PHARMS	1GM	N18683 001
>_ADD_>			APR 01, 1983
>_DLT_>	@ WHITEHALL ROBINS	1GM	N18683 001
>_DLT_>			APR 01, 1983

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL

	PERRIGO	120MG	N75153 001
			FEB 26, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
ZANTAC 75

+	GLAXO WELLCOME	EQ 75MG BASE	N20520 001
			DEC 19, 1995
+	WARNER LAMBERT	EQ 75MG BASE	N20520 001
			DEC 19, 1995

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

CUMULATIVE SUPPLEMENT NUMBER 3 MAR '99

NO MARCH 1999 APPROVALS

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Product Designations and Approvals List
March 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
166Ho-DOTMP TN=	Treatment of multiple myeloma.	NeoRx Corporation 410 W. Harrison Seattle, WA 98119 DD=02/10/1999
Alitretinoin TN= Panretin	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998 MA=02/02/1999
Atovaquone TN= Mepron	Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3.	Glaxo Wellcome Research and Development 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=08/14/1991 MA=01/05/1999
Autologous DNP-conjugated tumor vaccine TN= M-Vax	For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).	Avax Technologies, Inc. 4520 Main St. Suite 930 Kansas City, MO 64111 DD=02/23/1999
Bleomycin TN= Blenoxane	Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999

Orphan Product Designations and Approvals List
March 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Busulfan TN= Busulfex	As preparative therapy in the treatment of malignancies with bone marrow transplantation.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=07/28/1994 MA=02/04/1999
Coagulation factor VIIa (recombinant) TN= NovoSeven	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.	Novo Nordisk Pharmaceuticals, Inc. 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=06/06/1988 MA=03/25/1999
Decitabine TN=	Treatment of myelodysplastic syndromes.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands DD=03/08/1999
Decitabine TN=	Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands DD=03/08/1999
Denileukin diftitox TN= Ontak	Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/1996 MA=02/05/1999
Epoprostenol TN= Flolan	Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.	Glaxo Wellcome Inc. Five Moore Dr. PO Box 13398 Research Triangle Park, NC 27709 DD=03/22/1999

Orphan Product Designations and Approvals List
March 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Humanized MAb (IDEC-131) to CD40L TN=	Treatment of systemic lupus erythematosus.	Idec Pharmaceuticals Corporation 3030 Callan Rd. San Diego, CA 92121 DD=02/09/1999
Interferon beta-1a (recombinant human) TN= Avonex	Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) TN= 131IchTNT-1	Treatment of glioblastoma multiforme and anaplastic astrocytoma.	Techniclone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999
L-5-hydroxytryptophan TN=	Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA 91718 DD=01/20/1999
Lidocaine patch 5% TN= Lidoderm Patch	For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.	Hind Health Care, Inc. 3707 Williams Rd. Suite 101 San Jose, CA 95117 DD=10/24/1995 MA=03/19/1999
Murine MAb to polymorphic epithelial mucin, human milk fat globule 1 TN= Theragyn	Adjuvant treatment of ovarian cancer.	Antisoma West Africa House, Hanger Lane London W5 3QR United Kingdom DD=03/22/1999

Orphan Product Designations and Approvals List
March 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
N-acetylgalactosamine-4-sulfatase, recombinant human TN=	Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=02/17/1999
Pegylated arginine deiminase TN= Hepacid	Treatment of hepatocellular carcinoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=03/26/1999
Recombinant human C1-esterase inhibitor TN=	Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel Belgium, DD=02/23/1999
Recombinant human C1-esterase inhibitor TN=	Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel Belgium DD=02/23/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of solid organ transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of pancreatic islet cell transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/99
Sodium 1,3-propanedisulfonate TN=	Treatment of secondary amyloidosis.	Neurochem, Inc. 7220 Frederick Banting, Suite 100 Saint-Laurent, Quebec Canada H4S 2A1 DD=03/22/1999

DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO MARCH 1999 ADDITIONS

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 19TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

REFERENCES

NEW INDICATION

I-250	PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C
I-251	TREATMENT OF GENERALIZED ANXIETY DISORDER
I-252	NEW COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS METFORMIN
I-253	COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS INSULIN
I-254	PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS (LOSS OF BONE MASS)
I-255	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP)
I-256	USE IN TREATMENT OF SMALL CELL LUNG CANCER SENSITIVE DISEASE AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY
I-257	TREATMENT OF CHRONIC HEPATITIS B ASSOCIATED WITH EVIDENCE OF HEPATITIS B VIRAL REPLICATION AND ACTIVE LIVER INFLAMMATION

PATENT USE CODE

U-254	USE OF AGGRASTAT IN COMBINATION WITH HEPARIN
U-255	IMPROVED WAKEFULNESS IN PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY
U-256	TREATMENT OF HIV INFECITON IN COMBINATION WITH ONE OR MORE ADDITIONAL HIV ANTIVIRAL AGENTS
U-257	TREATMENT OF HIV INFECTION
U-258	TREATMENT OF NEURODEGENERATIVE DISEASES
U-259	TREATMENT OF ANDROGENIC ALOPECIA BY ORAL ADMINISTRATION OF DRUG SUBSTANCE
U-260	REDUCTION OF INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION WHO ARE INTOLERANT OF OTHER IOP LOWERING MEDICATIONS OR INSUFFICIENTLY RESPONSIVE TO ANOTHER IOP LOWERING MEDICATION
U-261	TREATING BENIGN PROSTATIC HYPERPLASIA WITH A GENUS OF COMPOUNDS, INCLUDING FINASTERIDE
U-262	TREATING BENIGN PROSTATIC HYPERTROPHY WITH FINASTERIDE

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020482 004	ACARBOSE;PRECOSE				I-252	SEP 29, 2001
						I-253	SEP 29, 2001
	020886 001	ALITRETINOIN;PANRETIN				ODE	FEB 02, 2006
						NCE	FEB 02, 2004
	020500 001	ATOVAQUONE;MEPRON				ODE	JAN 05, 2006
						I-255	JAN 05, 2002
	020711 002	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
	020711 003	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
	020954 001	BUSULFAN;BUSULFEX				ODE	FEB 04, 2006
						NDF	FEB 04, 2002
>ADD>	020998 001	CELECOXIB;CELEBREX	5760068	JUN 02, 2015	U-19		
>ADD>			5466823	NOV 30, 2013			
>ADD>			5563165	NOV 30, 2013			
>ADD>	020998 002	CELECOXIB;CELEBREX	5760068	JUN 02, 2015	U-19		
>ADD>			5466823	NOV 30, 2013			
>ADD>			5563165	NOV 30, 2013			
	020638 001	CIDOFOVIR;VISTIDE	5142051	JUN 26, 2010			
	020863 001	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
	020863 002	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
>ADD>	021041 001	CYTARABINE;DEPOCYT PRESERVATIVE FREE				ODE	APR 01, 2006
						NP	APR 01, 2002
	017922 001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	017922 002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	017922 003	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	018938 001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	018938 002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	019955 001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	019955 002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	020972 001	EFAVIRENZ;SUSTIVA	5811423	AUG 07, 2012	U-256		
			5519021	MAY 21, 2013			
			5663169	SEP 02, 2014	U-257		
	020972 002	EFAVIRENZ;SUSTIVA	5811423	AUG 07, 2012	U-256		
			5519021	MAY 21, 2013			
			5663169	SEP 02, 2014	U-257		
	020972 003	EFAVIRENZ;SUSTIVA	5519021	MAY 21, 2013			
			5663169	SEP 02, 2014	U-257		
			5811423	AUG 07, 2012	U-256		
	020375 001	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
	020375 002	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
	020375 003	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
	020375 004	ESTRADIOL;CLIMARA	5223261	JUN 29, 2010		I-254	MAR 05, 2002
	020908 001	ESTRADIOL;VAGIFEM				NP	MAR 26, 2002
	020992 002	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				NP	MAR 24, 2002
	020992 003	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				NP	MAR 24, 2002
	020527 003	ESTROGENS, CONJUGATED;PREMPRO 14/14	4826831	MAY 02, 2006			
			5547948	JAN 17, 2015			
	019304 002	FENOFIBRATE;TRICOR (MICRONIZED)	4895726	JAN 19, 2009			
	020747 001	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747 002	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020747 003	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747 004	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747 005	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747 006	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020788 001	FINASTERIDE;PROPECIA	5571817	NOV 05, 2013	U-259		
>ADD>			5886184	NOV 19, 2012			
>ADD>	020180 001	FINASTERIDE;PROSCAR	4760071	JUN 19, 2006	U-262		
>ADD>			5886184	NOV 19, 2012			
>ADD>			4377584	MAR 22, 2000	U-261		
>ADD>	020974 001	FLUOXETINE HYDROCHLORIDE;PROZAC	4314081	FEB 02, 2001			
>ADD>			4626549	DEC 02, 2003			
>ADD>	020974 002	FLUOXETINE HYDROCHLORIDE;PROZAC	4314081	FEB 02, 2001			
>ADD>			4626549	DEC 02, 2003			
	020882 001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
			5084479	JAN 02, 2010	U-258		
	020882 002	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
			5084479	JAN 02, 2010	U-258		
	020083 001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
	020657 001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
>ADD>	020966 001	ITRACONAZOLE;SPORANOX	4267179	JUN 23, 2000			
			4791111	DEC 23, 2005			
	020564 002	LAMIVUDINE;EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
			5532246	JUL 02, 2013	U-250		
	020596 002	LAMIVUDINE;EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
			5532246	JUL 02, 2013	U-250		
	020764 001	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
	020764 002	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
	020764 003	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
>ADD>	020597 001	LATANOPROST;XALATAN	5296504	MAR 22, 2011	U-260		
>ADD>			5422368	MAR 22, 2011	U-260		
>ADD>			4599353	JUL 28, 2006	U-260		
	020612 001	LIDOCAINE;LIDODERM				ODE	MAR 19, 2006
	019777 006	LISINOPRIL;ZESTRIL	4374829	DEC 30, 2001			
	019643 002	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
	019643 003	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
	019643 004	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
>ADD>	020969 001	METHOXSALEN;UVADEX	4845075	APR 11, 2009		NP	FEB 25, 2002
>ADD>			5036102	APR 11, 2009			
>ADD>	020682 001	MIGLITOL;GLYSET	4639436	JAN 27, 2009	U-111		
>ADD>	020682 002	MIGLITOL;GLYSET	4639436	JAN 27, 2009	U-111		
>ADD>	020682 003	MIGLITOL;GLYSET	4639436	JAN 27, 2009	U-111		
	020717 001	MODAFINIL;PROVIGIL	4177290	MAR 09, 1999			
			5618845	OCT 06, 2014	U-255		
			4927855	MAY 22, 2007	U-255		
	020717 002	MODAFINIL;PROVIGIL	4177290	MAR 09, 1999			
			5618845	OCT 06, 2014	U-255		
			4927855	MAY 22, 2007	U-255		
	018612 003	NICOTINE POLACRILEX;NICORETTE (MINT)				NP	DEC 23, 2001
	020066 003	NICOTINE POLACRILEX;NICORETTE (MINT)				NP	DEC 23, 2001

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020897 001	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
	020897 002	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
>ADD>	020553 001	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
>ADD>			5656295	FEB 05, 2008			
>ADD>	020553 002	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
>ADD>			5656295	FEB 05, 2008			
>ADD>	020553 003	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
>ADD>			5656295	FEB 05, 2008			
>ADD>	020553 004	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
>ADD>			5656295	FEB 05, 2008			
	020031 001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031 002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031 003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031 004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031 005	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020710 001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885 001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885 002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885 003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885 004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020936 001	PAROXETINE HYDROCHLORIDE;PAXIL CR	4839177	JUN 13, 2006		NDF	FEB 16, 2002
>ADD>			5422123	JUN 06, 2012			
>ADD>			4721723	DEC 29, 2006			
			5872132	MAY 19, 2015			
>ADD>	020936 002	PAROXETINE HYDROCHLORIDE;PAXIL CR	4839177	JUN 13, 2006		NDF	FEB 16, 2002
>ADD>			5422123	JUN 06, 2012			
>ADD>			4721723	DEC 29, 2006			
			5872132	MAY 19, 2015			
	020698 001	POLYETHYLENE GLYCOL 3350;MIRALAX				NP	FEB 18, 2002
	020639 004	QUETIAPINE FUMARATE;SEROQUEL	4879288	MAR 20, 2007		NCE	SEP 26, 2002
	020272 007	RISPERIDONE;RISPERDAL	5158952	DEC 29, 2007	U-90	D-37	OCT 17, 2000
			4804663	DEC 29, 2007	U-90		
	020912 001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAY 14, 2012	U-230		
			5880136	SEP 27, 2010	U-254		
	020913 001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAY 14, 2012	U-230		
			5880136	SEP 27, 2010	U-254		
	020671 001	TOPOTECAN HYDROCHLORIDE;HYCAMTIN				I-256	NOV 30, 2001
	020699 001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
	020699 002	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
	020699 003	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
	020699 004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
	019614 004	VERAPAMIL HYDROCHLORIDE;VERELAN	4863742	JUN 19, 2007			
>ADD>	020943 001	VERAPAMIL HYDROCHLORIDE;VERELAN PM	4863742	JUN 19, 2007			
>ADD>	020943 002	VERAPAMIL HYDROCHLORIDE;VERELAN PM	4863742	JUN 19, 2007			
>ADD>	020943 003	VERAPAMIL HYDROCHLORIDE;VERELAN PM	4863742	JUN 19, 2007			

*U.S. Government Printing Office: 1999 — 454-723/00010